

July 14, 2000

Stuart L. Nightingale, M.D.
Office of the Assistant Secretary for Planning and Evaluation
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20101

Dear Dr. Nightingale:

I am a registrant for the Conference on Human Subject Protection and Financial Conflict of Interest on August 15th and 16th. I am attending both as the Chief Operating Officer and General Counsel of The Schepens Eye Research Institute, an NIH grantee institution (primarily through the National Eye Institute), and in my capacity as Chair of the Commercial Relations Committee of the Association for Research in Vision and Ophthalmology. I am also particularly interested in the subject matter of the Conference because I am responsible for industrial relations here at the Institute, and in a past position (General Counsel, Dana-Farber Cancer Institute), I served as a non-voting participant on that institution's IRB.

Pursuant to the Call for the Conference, I am responding to the Six Questions posed in the Notice.

Question #1 I am somewhat unclear as to information being solicited through this question. What I believe is being asked is, "What are the kinds of financial interests that may affect the behaviors of the participants identified?" With this in mind, I would answer as follows:

Clinical Investigators: Do they have a consulting relationship or equity holdings in a company which is sponsoring the human studies research? Do they have a similar interest with a company which owns a competing technology? If the answer to either of these questions is in the affirmative, what is the magnitude of the interest? If the interest involves equity, is the company

privately or publically held? Have they invented the technology, and therefore stand to gain from its success, and conversely, have they invented a competing technology?

IRB Members and Staff: Similar analysis as above.

Awardee Institutions: Does the institution have an equity holding (e.g., in its endowment) in the company sponsoring the research, or in a company with a competing technology. Is the reporting relationship of the IRB leadership and staff independent of senior institutional officials having responsibility for overseeing equity holdings?

Question #2 I am not aware of the existence of empirical evidence on these questions, although I assume studies addressing at least some of these questions have been undertaken.

Question #3 Disclosure should only involve "conflicting" financial interests and should be made in a general way (e.g., "I consult for the XYZ company which is sponsoring this trial." "I have received equity in the sponsoring company as a result of the licensing arrangement for the technology." It is my belief that informed consents are often so detailed and comprehensive that the prospective subjects may 'lose sight of the forest for the trees'. ") The fact of the relationship is what is important. If the subject desires more information, s/he can ask, and the investigator's response should be documented. I believe conflicts at the IRB level should be handled by excusing that member from the deliberations relating to the study wherein the conflict lies. If there is a significant financial conflict at the institutional level (e.g., the awardee institution owns 10% of the sponsoring company's equity), then that information should be disclosed in the consent form. I believe a critical issue here is magnitude of the holding. I generally think information regarding protections in place should be made only if the subject inquires about them. Regarding levels of interest, I want to reserve my comments for now.

Question #4 I have in part answered this question earlier. I think the consent form is the appropriate place for disclosure, with the subject having the ability to speak to either or both the investigator or a responsible institutional official about the matter. The consent should be worded in a way to encourage such inquiry.

Question #5 The institution must play the lead role in establishing a climate of objectivity--with appropriate disclosures, organizational "protection" for those individuals responsible for the policies in this area and the establishment of sanctions for those individuals who willfully ignore the policies. The government should periodically audit institutional practices, but not in a "right-wrong" way. There are a variety of procedures and policies that could be employed in this area and institutional discretion should be permitted and encouraged. Having an oversight program in place, with mandatory continuing education for all participants, organizational "respect" for the implementing staff and sanctions for noncompliers are the essential elements of the programmatic foundation. In general terms, there does need to be respect for the privacy of certain financial information, so inter-institutional sharing of information must be carefully studied. There is a real concern that individuals will "go underground" with their conflicts if privacy issues are not appreciated or the rules are viewed as too unreasonable.

Question #6 The conflicts rules should be established "across the board" in my view--irrespective of source of funding. Different standards for different granting relationships will create significant compliance problems and undercuts the legitimacy of the policies

I look forward to attending this Conference and appreciate your efforts in organizing it.

Sincerely,

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and General Counsel
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